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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,101	03/25/2004	Gregor Sagner	022101-001910US	8546

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	**PAPER NUMBER**
1637	
MAIL DATE	**DELIVERY MODE**
07/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/810,101	SAGNER ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 December 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the office action filed on May 15, 2007 is considered and acknowledged.

Status

2. Claims 9-14 are pending. Claims 1-8 are canceled. All arguments have been thoroughly reviewed and deemed persuasive for the reasons that follow. This action is made Non-Final.

Informalities

3. The following informalities are noted:

(i) Claim 13 recites the abbreviation 'FRET'. It is advised to expand the abbreviation as 'fluorescence resonance energy transfer' .

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 9-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1-10 of U.S. Patent No. 6,691,041 ('041) in view of Lowe et al. (WO 99/54510). Although the conflicting claims are not identical, they are not patentably distinct from each other because an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed.Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim 9-11 are generic to all that is recited in claims 1-7 of the patent ('041). That is, the claims 1-7 ('041) fall entirely within the scope of claims 9-11 or in other words, claim 9-11 are anticipated by the claims 1-7 of the patent ('041). Specifically the method of steps (a) through (d) disclosing a method for absolute quantitation of a target nucleic acid relative to a reference nucleic acid comprising are within the scope of the claims 1-7 of the patent ('041). Further the instant claims 12-14 are generic to all that is recited in the claims 8-10 of patent ('041), The only variation in the instant invention with that of the patent ('041) is that, the patent ('041) does not disclose dilution series of target and reference nucleic acid.

Lowe et al. teach a method for determining a quantitative measure of an amplification of a target nucleic acid comprising the steps of (a) preparing a dilution series of the target nucleic acid and reference nucleic acid (see page 3, line 12-14, page 6,

line 20-28, page 11, line 24-35, page 13, line 30-39, page 14, line 1-19);(b) amplifying the target and reference nucleic acid under defined conditions and measuring the amplification in real-time (see page 3, line 14-25, page 13, line 30-39, page 14, line 1-19);(c, d) setting a defined signal threshold value and determining for each dilution, the cycle number at which the signal threshold value is exceeded (threshold cycle for each dilution) (see page 3, line 25-27, page 10, line 16-23); (f) calculating the amplification equivalent in each dilution series and normalizing the RNA equivalent to provide normalized RNA equivalent standard curve. (see page 3, line 29-33, page 10, lines 31-39); quantifying the amount of target nucleic acid relative to the reference nucleic acid (see page 13, line 30-39, page 14, line 1-19); quantitation of a target nucleic acid using internal standard or reference nucleic acid (see page 13, line 10-39).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of determining the efficiency of amplification and quantitating a target nucleic acid as taught by patent (' 041) with a step of preparing dilution series of target and reference nucleic acids as taught by Lowe et al. to achieve expected advantage of developing an improved sensitive method for quantitating a target nucleic acid because Lowe et al. explicitly taught preparing dilution series of target and reference nucleic acids, calculating the amplification equivalent in each dilution series and normalizing the target nucleic acid equivalent to provide normalized target nucleic acid equivalent standard curve and quantifying the amount of target nucleic acid relative to the reference nucleic acid (see page 3, line 29-33, page 10, lines 31-39, page 13, line 30-39, page 14, line 1-19). An ordinary practitioner would have been motivated to combine the method of

determining the efficiency of an amplification of a target nucleic acid and quantitation of said nucleic acid as taught by the patented claims with the inclusion of dilution series as taught by Lowe et al. because an ordinary practitioner would have a reasonable expectation of success that the combination would result in normalizing and calibrating the target nucleic acid in relation to each dilution factor relative to a reference nucleic acid for enhancing the sensitivity of quantitation of a target nucleic acid and such modification of the method is considered obvious over the cited prior art. Therefore the instant claims are obvious over the claims in the patent ('041).

Response to arguments:

5. With regard to the rejection of claims 9-14 under obviousness type of double-patenting, Applicants' arguments and terminal disclaimer are fully considered and the rejection is withdrawn herein in view of the terminal disclaimer.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Prabha Chunduru 7/20/07
SURYAPRABHA CHUNDURU
PRIMARY EXAMINER